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PATENT APPLICATION  
Attorney's Docket No.: 0746.1024-006  
(UMMC91-03A2)

#H #38

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Harriet L. Robinson, Ellen F. Fynan, Robert G. Webster and Shan Lu  
Application No.: 08/187,879 Group: 1633  
Filed: January 27, 1994 Examiner: D. Clark  
For: IMMUNIZATION BY INOCULATION OF DNA  
TRANSCRIPTION UNIT

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
Date	Signature
04/14/00	<i>Lisa Jensen</i>
Lisa Jensen	
Typed or printed name of person signing certificate	

DECLARATION UNDER 37 C.F.R. 1.132 OF SHAN LU, M.D.

Box AF

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

I, Shan Lu, M.D., of 112 Northgate Road, Northboro, Massachusetts 01532, hereby declare and state that:

1. I am a named inventor on the referenced patent application.
2. I understand that the claims of the referenced patent application have been rejected, in part, because the constructs described in the Declaration under 37 C.F.R. 1.132 of Dr. Harriet L. Robinson, filed 2/28/96 (the "Data Declaration"), are believed by the

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Examiner to have different epitopes from the constructs described in the specification of the application.

3. I have reviewed the description of the constructs in the Data Declaration and in the specification. To facilitate comparison of the constructs, certain features of each type of construct are described herein.
4. Certain constructs are based on the SIV proviral DNA and SIV239.dpol insert (Figures at p. 39 of the Appendix to the Data Declaration, which correspond exactly to Figures 16A and 16B of the specification). Both the Data Declaration and the specification indicate that the SIV239.dpol insert was generated from two separate plasmids representing the 5' (p239SpSp5') and 3' (p239SpE3') halves of a 239 provirus (p. 1 of the Appendix to the Data Declaration, and p. 53, lines 21-26 of the specification).
5. Other constructs are based on plasmid JW4303 (p. 2-3 of the Appendix to the Data Declaration, and p. 52, lines 8 *et seq.* of the specification). Both the Data Declaration and the specification indicate that the constructs were constructed by cloning polymerase chain reaction (PCR)-amplified fragments of the SIV env sequences (shown in the Figures at p. 39 of the Appendix to the Data Declaration, which, as stated above, correspond exactly to Figures 16A and 16B of the specification).
6. The nomenclature for certain of the constructs described in the Data Declaration and in the specification depended, in part, on the relative size of the protein expressed by the construct, when the protein was examined by polyacrylamide gel electrophoresis (PAGE). For example, in the following constructs, the relative size of the expressed protein is underlined: SIV239.sgp110, SIV239.sgp130, SIV251.sgp130, SIV316.sgp130 (Appendix to Data Declaration) and SIV239.sgp120, SIV239.sgp140, SIV251.sgp140, SIV316.sgp140 (specification). The size of a protein, as determined by PAGE, is a relative size, and can be affected by various factors, including electrophoresis conditions or glycosylation of proteins, for example. The differences in the names of the proteins described in the Data Declaration and in the specification are due to their relative size during PAGE analysis, rather than due to any substantive difference in the proteins

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expressed by each construct. This is emphasized by the nomenclature for the constructs used in Table 1 of the Appendix to the Data Declaration, which is exactly the same as the nomenclature of the constructs described in the specification.

7. Based on the above discussion, I conclude that the proteins encoded by the constructs described in the Data Declaration and by the constructs described in the specification are *exactly* ~~essentially~~ the same as one another, and would be expected to have the same relevant epitopes as one another.

I further declare that all statements made herein of my knowledge are true and that all statements made on other information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

  
Shan Lu

4/14/2000  
Date